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09/707,919	11/08/2000	Samir Kumar Brahmachari	39562-175772	9079

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/707,919

Applicant(s)

BRAHMACHARI ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

For example on page 9 and 10 of the specification contains hyperlinks.

2. The specification also recites that the SNPs (A) and (B) are provided in bold of the sequence on pages 10 and 11. This bold does not appear to be visible. Perhaps applicant may wish to underline the positions to highlight their position.

### ***Sequence Rules***

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The sequence on page 10 and 11 of the specification does not appear in the sequence listing and is not identified by SEQ ID NO:. Appropriate correction is required.

Furthermore, the drawings contain numerous sequences which are not identified by SEQ ID NO:. Appropriate correction is required.

***Claim Objections***

4. Claim 2 is objected to because the claim contains more than one period. The claim contains three periods, one at the end of the third line of the claim, one after step a and finally one at the end of the claim. Appropriate correction is required.
5. Claims 2, 3, 4, 7, 8, 9 contain "as listed in SEQ ID NO: 1". This recitation is redundant and may be deleted to provide a more concise claim.

***Claim Rejections - 35 USC § 112- Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-5 are indefinite because the claims do not recite a positive process step which clearly relates back to the preamble. The preamble states that the method is for detection of human SCA2 variants but the final process step is predicting the risk or susceptibility to SCA2 disease based upon the haplotype. Therefore the claims are unclear as to whether the method is a method of detection of variants or predicting a risk or susceptibility. In the event that applicant wishes to claim a method for determining a risk for SCA2 disease, the method steps of a, d, e, and f appear to have already been done and are not necessary since applicant has performed the association study. A method of determining a risk for SCA2 disease by amplifying

gDNA of SCA2 patients, analyzing the PCR products at position 107 and 178 of SEQ ID NO: (\*\* of sequence on page 10 and 11), wherein the detection of a G at position 107 and a T at position 178 is indicative of a lower risk of developing SCA2 and the detection of a C at position 107 and a C at position 178 is indicative of a high risk of developing SCA2. As written the claim appears to contain not only the method which may be used by other artisans, but also the method in which applicants have identified the instant invention.

B) Claims 1-5 are indefinite because they contain "gene variants and the". It is unclear how these words relate. Deletion of "and the" may clarify the method.

C) Claims 2, 3, 4 is indefinite because the claim is in improper Markush format. As provided by the MPEP, "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925)." The instant claims are drawn to "are selected from the group". Addition of "consisting of" would correct the Markush type language and provide clarity for the claims. Claims 3 and 4 also contain an extra "and" in the listing. An "and" is supposed to precede the last element of the group. Deletion of the and after SEQ ID NO: 7 and the "and" after SEQ ID NO: 12 would overcome this rejection.

D) Claim 2 is indefinite because the claim is directed to polymorphic sites, however Claim 1 is directed to variants. It is unclear whether the polymorphic sites are

the same as the variants. In the event that they are the same, amendment to one or the other terms would provide consistency. Furthermore, it unclear whether the SEQ ID NO:1 and 2 are polymorphic sites or whether they are primers, the sentence is not clear. Thus, the metes and bounds of the claimed invention are unclear.

E) Claim 3 is indefinite because "the allele specific primers" lacks proper antecedent basis. Claim 1 refers to oligonucleotide primers for amplification of exon 1 of the human SCA2 gene, however, the claim does not refer to allele specific primers. Allele specific primers are generally thought of as primers which are capable of determining the residue present at a position rather than primer which amplify the entire exon. Similarly, the claim does not recite "allelic variants" so the recitation lacks proper antecedent basis. Appropriate correction is required.

F) Claim 5 is indefinite because the claims are directed to closed language primers and probes. The language "are" is indicative of "consisting of language" such that there are no residues on either side of the oligonucleotide. Therefore, claim 5 is confusing how there could be 5 bases to 100 bases. The probes and primers are not these lengths. Either the claim needs to be drawn to open claim language such as "comprising" or the needs to be amended in another way. In the event that applicant uses "comprising" the lower boundary for the oligonucleotide would vary depending upon the length of the individual probes and primers.

G) Claim 6 is indefinite because it is unclear whether the kit comprises any one, one or more of SEQ ID NO: 1-12, or requires a collection of each of these sequences. This claim also appears to be missing a word or phrase prior to "are selected".

Moreover, "given under SEQ ID NO: 1-12" is unclear. It is unclear what "given under" is indented to mean. Deletion of this recitation may help clarify.

H) Claim 7 is in improper Markush format. Markush type claims are designed to be a closed set. Amending the claim to recite "selected from the group consisting" of would overcome this rejection. An "and" is supposed to precede the last element of the group. Deletion of the and after SEQ ID NO: 1 would overcome this problem. It is unclear whether the primers are intended to allow for additional nucleotides on the ends of the probe, i.e. open claim language.

I) Claims 8 and 9 are in improper Markush format. Markush type claims are designed to be a closed set. Amending the claim to recite "selected from the group consisting" of would overcome this rejection. Deletion of the and after SEQ ID NO: 7 and 11 would overcome this problem. It is unclear whether the primers are intended to allow for additional nucleotides on the ends of the probe, i.e. open claim language.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Imbert, et al (Genbank Accession Number Y08262, January 1997).

This rejection is applied when the claims are drawn to primers, probes or oligonucleotides comprising SEQ ID NO: 1-12.

Imbert et al (herein referred to as Imbert) teaches a nucleic acid sequence of the gene for spinocerebellar ataxia 2. The nucleic acid taught by Imbert is a nucleic acid comprising SEQ ID NO: 2 (positions 433-414), 4 (positions 51-81), 5 (positions 60-80), 7 (positions 121-152), 8 (positions 130-151), 10 (positions 68-94), 12 (positions 139-165). Therefore, Imbert teaches each limitation of the claimed invention.

8. Claims 8-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Muzney et al (Genbank Accession Number AC1004085, November 6, 2000).

This rejection is applied when the claims are drawn to primers, probes or oligonucleotides comprising SEQ ID NO: 1-12.

Muzney et al (herein referred to as Muzney) teaches a nucleic acids sequence from human which comprises SEQ ID NO: 3 (positions 89335-89305), 6 (positions 89265-89234), 9 (positions 89318-89292), and 11 (positions 89247-89221). Therefore, Muzney teaches each limitation of the claimed invention.

9. Claims 8-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Pulst et al (Genbank Accession Number U70323, November 1996).



This rejection is applied when the claims are drawn to primers, probes or oligonucleotides comprising SEQ ID NO: 1-12.

Pulst et al (herein referred to as Pulst) teaches a nucleic acid sequence for SCA2. The nucleic acid taught by Pulst comprises at least SEQ ID NO: 1 (positions 375-398), 2 (positions 833-814) and 12 (positions 539-565). Therefore, Pulst teaches each limitation of the claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pulst et al (Nature Genetics, Vol 14, pages 269-276, November 1996).

Pulst et al (herein referred to as Pulst) teaches an expansion of a normally biallelic trinucleotide repeat in SCA2. Pulst teaches primers SCA2-A and SCA2-B, as illustrated in Figure 2, which amplify the CAG repeat region.

Pulst does not specifically teaches SEQ ID NO: 1 and 2 of the instant application as primers.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologues, however, the court stated

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologues because homologues often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

Since the claimed primers simply represent functional homologues of the full length disclosed SCA2 sequence concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited reference in the absence of secondary considerations.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified primers of Pulst to obtain alternative primers with the same function of amplifying the gene. Primer design is well

known in the art. The skilled artisan would have been motivated to have designed alternative primers which amplify the region of the CAG repeats identified by Pulst. The instant application claims primers which are at positions 375-398 and 833-814 of the SCA2 gene taught by Pulst. These primers target regions which flank the CAG repeat region. Therefore, the primers would function to amplify the CAG repeat region, just as the primers of Pulst function to amplify the CAG repeat region. Therefore, the primers SEQ ID NO: 1 and 2 represent functional equivalents to the primers SCA2-A and SCA2-B of Pulst.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pulst et al (Nature Genetics, Vol 14, pages 269-276, November 1996) as applied to Claim 7 above, and further in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

Pulst does not specifically teaches packaging necessary reagents into a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Pulst with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Pulst into a kit, as taught by Ahern for the express purpose of saving time and money.

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***Conclusion***


**13. No claims allowable.**

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday 7:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg   
February 4, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600